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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/459,022	12/10/1999	MING CHENG	38-21(15084)	9594

27161 7590 05/21/2003

MONSANTO COMPANY
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ST. LOUIS, MO 63167

EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/459,022

Applicant(s)

CHENG ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 11 February 2003, paper number 14. Applicant has cancelled claims 4, 6, and 10-17, and amended claims 1-3, 5, and 7-9. Claims 1-3, 5, and 7-9 are pending, and are examined in the instant action.
2. This action is made FINAL necessitated by Applicant's amendment.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112-second paragraph

5. Claims 1-3, 5, and 7-9 are rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

In claim 1, and all claims dependent thereon,

- In step (a), the Markush grouping is unclear.
- In step (a), "capable of identifying" is unclear. How is a genetic component capable of identifying a cell or tissue?

- "a transformed plant cell or tissue to be introduced into the plant cell or tissue" is not clear. What does this mean? How can a plant tissue be introduced into a plant cell?

In claim 3, "the co-culture step" lacks antecedent basis.

In claims 7-9, "about" is unclear, because the metes and bounds of "about" are not defined.

Claim Rejections - 35 USC § 112

6. Claims 1-3, 5, and 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim language in question is: "the group consisting of immature embryos or embryogenic callus from wheat or maize and hypocotyl sections of callus cell suspension cultures from soybean", "capable of identifying a transformed plant cell or tissue to be introduced into the plant cell or tissue", "a vessel not containing media", "the addition of water in an amount of between 50-300 microliters to said vessel at the co-culture step" and "the co-culture period". Applicant is invited to point out the page and line number in the specification where "the group consisting of immature embryos or embryogenic callus from wheat or maize and

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hypocotyl sections of callus cell suspension cultures from soybean", "capable of identifying a transformed plant cell or tissue to be introduced into the plant cell or tissue", "a vessel not containing media", "the addition of water in an amount of between 50-300 microliters to said vessel at the co-culture step" and "the co-culture period" can be found. Absent such support, Applicant is required to cancel the new matter in response to this Office Action.

7. Claims 1-3, 5, and 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification,

- while being enabling for adding 100–300 microliters of water at the co-culture step, wherein the weight of the Agrobacterium-inoculated explant is reduced by up to 30% during the co-culture period,

does not reasonably provide enablement for

- all conditions that decrease the weight of Agrobacterium inoculated explants.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The breadth of applicant's claims encompass all conditions known to decrease weight of an explant, with an upper limit of 30% reduction, including physical removal of plant tissue from the experiment.

Applicant shows adding water in an amount of 100-300 microliters, at the coculturing step, will result in increased number of Gus spots, indicative of increased transformation efficiency.

The state of the art indicates that it is unpredictable as to what methods of decreasing the weight of the explant would increase transformation efficiency. It is unpredictable what amount of water should be added to the coculturing medium to decrease the weight of the explant.

In fact, Table 3 (p 21-22. specification) shows that only the 100-300 microliters water addition conditions increased transformation efficiency.

Re the "co-culture period": Applicant claims no limitation on this time period—it can be instantaneous or infinitely long. It is well known in the art that culture conditions of tissue to which no media is added, or no water added, over time lead to desiccation and deleterious effects on tissue. It is unpredictable that any time period would function as desired. Finding proper conditions would require a myriad of experiments and would impose undue burden on one of ordinary skill of the art. As evidence of the importance of this, applicant claims specified time periods in dependent claims 6, 7 and 8.

In view of the breadth of the claims (any plant, any conditions than decrease the weight to the explant, and any percentage weight reduction) and the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

8. Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Chee, P, et al, in *Agrobacterium Protocols*, K. Gartland and M Davey, eds, (1995) Humana Press, Totowa, NJ, pages 101-119, for reasons of record.

Applicant traverses, stating primarily that Chee does not disclose any such method as it might apply to wheat or maize immature embryos embryogenic callus of soybean callus or suspension cultures or hypocotyls regions. Applicant's traversal has been considered and is unpersuasive because Chee teaches inoculation of soybean cotyledons, and adjacent regions (p.107).

Accordingly, Chee anticipates the claimed invention.

9. Claims 1 and 2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Somerville, et al, US 5,668,292, issued September 16, 1997, for reasons of record.

Applicant traverses, stating primarily that Sommerville teaches a method which utilizes media throughout and not a co-culture step without medium, citing Sommerville at col 25, 26, and 35, and Table 3. Applicant's traversal has been considered and is unpersuasive because Sommerville teaches a method comprising coculture without medium (col 26, lines 1-3).

Accordingly, Somerville anticipates the claimed invention.

Remarks

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

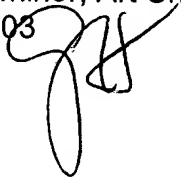
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

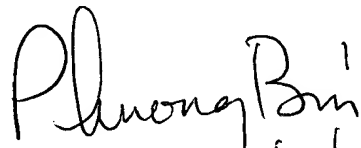
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L Helmer PhD
Patent Examiner, Art Unit 1638
May 19, 2003




PHUONG T. BUI
PRIMARY EXAMINER 5/19/03